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14. ABSTRACT

The Fluid Intake Monitor (FIM) measures fluid consumed from a bladder hydration system. Bench and field tests were performed to assess reliability and validity of the FIM, Fluid volumes of FIM were compared to scale-weighed volumes of water. Bench Test Results: an absolute percent error existed ($p < 0.001$) between sips, with the FIM significantly overestimating the first sip ($p < 0.01$) compared to the subsequent nine sips. A significant intraclass reliability coefficient (ICC) = 0.83 was achieved for trials 2 through 10. There was no difference in mean sip volume measured using the FIM vs. the scale (25.7 + 10.7 ml vs. 25.6 + 8.7 ml, respectively). Field Test Results: of 31 trials, 4 trials under-measured water consumption in excess of 15% (29.4% to 47.1%), and two trials over-measured water consumption in excess of 15% (15.5% and 16.6%). These units were neither reliable nor valid for use in the field. Software and hardware modifications identified should significantly improve FIM performance.

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Fluid Intake Monitor, Hydration, Water Consumption, Drink-O-Meter, Reliability, Validity, Test and Evaluation, Canteen, Hydration System

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USARIEM TECHNICAL REPORT 09-04

RELIABILITY AND VALIDITY OF A PROTOTYPE FLUID INTAKE MONITOR

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EXECUTIVE SUMMARY

Maintaining optimal hydration is an important part of sustaining the health and performance of the Warfighter. Previous research has shown that either too little (hypohydration) or too much (hyperhydration) fluid intake can affect the health of the Warfighter and lead to cognitive and physical performance decrements. In extreme cases, too little or too much fluid can even lead to death. The U.S. Army continues to update hydration intake guidelines to help prevent over- or under-consumption of fluids. The Fluid Intake Monitor (FIM) is a device that measures fluid consumed through a collapsible bladder-type body-worn hydration system. The FIM can provide information on how much fluid was consumed by an individual. The FIM can be used as a stand-alone device or as part of the Warfighter Physiological Status Monitoring (WPSM) system of networked sensors that measure physiological and event information from individual Warfighters during training or in theater. **Objective:** The purpose of this study was to determine the reliability and validity of the current prototype version of the FIM. **Methods:** Bench and field tests were performed. During the bench test, 27 FIM units were tested. The test consisted of a technician taking 10 sips from each FIM. Volumes of each sip determined by the FIM were compared to sip volume measured gravimetrically with a calibrated scale. The scale method served as a criterion or "gold standard" to which the accuracy of the FIM measurements was compared. One milliliter of water was assumed to weigh 1 gram. Reliability was calculated using test-retest procedures (intraclass reliability). Validity was determined by a t-test of the mean volume measured by the FIM vs. mean volume assessed gravimetrically. A Bland-Altman analysis-plot compared the variability of the test device to the gold standard. The field test was conducted with 12 volunteers who used 15 FIM units. Each FIM was used for 24 hours with volunteers drinking from the FIM during their normal daily activities. Volume of fluid consumed was measured after each 24 hours of the test, or when the volunteer emptied the hydration system bladder (whichever occurred first). Measurements included the post – pre-weight change and the volume of fluid recorded from the downloaded FIM data. Regression analysis was conducted to determine variances in the measurements and to assist in determining the accuracy of individual measurements of total volume. **Results:** Bench Test: a significant difference in absolute percent error existed ($p < 0.001$) between sips, with the FIM significantly overestimating the first sip ($p < 0.01$) compared to the subsequent nine sips. Air in the drinking line was hypothesized to be the cause, with this air spinning the gears upon the first sip. Once the system was primed, the error was reduced and percent error did not differ significantly among sips 2 through 10. A significant intraclass reliability coefficient (ICC) = 0.83 was achieved for trials 2 through 10. There was no difference in mean sip volume measured using the FIM vs. the scale (25.7 $\pm$ 10.7 ml vs. 25.6 $\pm$ 8.7 ml, respectively). Fifteen of the 27 units tested had percent error of the volume of all 10 sips that exceeded the 5% criterion. Field Test: 12 volunteers completed 31 trials using the 15 most accurate units identified by the bench test. Some volunteers participated in two or more trials with a given FIM,

and three volunteers tested two different units. Of the 31 trials, 4 trials had the FIM under-measuring water consumption in excess of 15% (29.4% to 47.1%), and two trials had the FIM over-measuring water consumption in excess of 15% (15.5% and 16.6%). **Conclusion:** In summary, these prototype FIMs were neither reliable nor valid for use in the field. There was also great variability between units. It appears that the FIM's gear-type flow sensor design was appropriate. Software and hardware modifications were identified which should significantly improve FIM performance.

INTRODUCTION

Maintaining adequate hydration is an important part of maintaining health especially under extreme operational and environmental conditions where medical assistance might not be readily available. Water accounts for approximately 72% of body weight (17). Water balance is achieved by balancing water influx and efflux. Water influx comes from the diet (water in food and fluids consumed), water produced during metabolism, and water entering the body through the skin and respiratory tract. Water is lost through urine, skin sweating, respiration, and feces (17). Maintaining adequate water intake can be challenging for individuals who are physically active, work in hot environments, or wear occlusive protective clothing.

Over- and under-hydration can have various negative consequences. Excess water intake can lead to water intoxication or hyponatremia (18, 22) while not consuming enough water leads to hypohydration, which can predispose individuals to heat illness such as heat exhaustion and heat stroke (26), and can even lead to death (6). Research has shown that deviations greater than ~2% in body water can lead to cognitive, mood, and neurophysiological changes whether due to dehydration (7, 19, 28) or hyponatremia from over-drinking (23, 24). Physical performance impairments associated with hypohydration (25, 26) and hyperhydration (23) have also been observed.

Historically, heat injuries resulting from dehydration have been a problem for the military (8, 29). Within the past 25 years, the importance of water consumption during military training has led to prophylactic water consumption with military leaders being required to enforce fluid replacement guidelines (10, 11, 18). However, without specific guidance on environmental factors and work rates, the reverse problem of overdrinking leading to hyponatremia can occur (18). As a result, specific guidelines were developed for military leaders to follow that prescribe how much water should be consumed for various combinations of environmental condition and work rate, to prevent both under-consumption and over-consumption of fluids (22). Current Army doctrine regarding fluid replacement in heat stress control and heat casualty management is found in Army Technical Bulletin TB MED 507 (12). Still, knowing how much a Warfighter has actually consumed is a challenge. From 2002 to 2006 there was an increase in hyponatremia incidents in U.S. military members, and only a slight decrease from 2006 to 2007 (145 cases reduced to 134 cases) (1).

Ways of non-invasively measuring fluid intake could help ensure individuals do not over- or under-consume fluids. One approach to measuring the amount of fluid consumed is through the use of Fluid Intake Monitor (FIM) technologies to monitor fluid consumption. These devices can be used to ensure that Warfighters consume recommended/appropriate amounts of water (5), and to tailor logistical support to actual water needs, as water is expensive to transport. Ideally, direct measures of tissue hydration would guide water intake practices (16). However, even simple measures of hydration, e.g., nude body weight changes, are currently impractical methods of estimating total body water changes in the field.

Sweat losses can be estimated through predictive biomedical modeling. These models use weather measurements, work rate, Warfighter characteristics, (e.g., height, weight, heat acclimation state), clothing (insulation, water permeability), and weight carried (clothing and equipment) inputs to predict sweat rates and total water requirements (13, 20). While, troops may be instructed on the proper amount of fluid to consume, presently there is no monitoring system that allows commanders or medics to verify it actually occurred. The FIM may be a useful tool to provide that verification. Furthermore, current doctrine guidelines are based on consumption of fluid from hard canteens (12), whereas troops increasingly use the collapsible hydration systems (e.g., Camelbak™ (Petaluma, CA) hydration system). The FIM was designed for use with these types of hydration systems.

Over the past 10 years, USARIEM has worked on various FIM prototypes. The first technology explored was a differential pressure transducer that did not produce accurate measurements. A second system was a flow meter device that had an unacceptable flow resistance. The next development came with an early validation study of a turbine-based FIM, sometimes called the Drink-O-Meter. A high correlation ($R^2 = 0.99$) between bench test measured water withdrawn at varying volumes, rates, and flow patterns and that recorded by the Drink-O-Meter was observed with this system (9). However, average error rates were above acceptable limits, with errors averaging 8.9 $\pm$ 7.8%. Linear and valid results were produced when sip velocities exceeded 9 ml per second, but unacceptable measurement errors existed for slow extended sips (21). The error rates were due to turbine failures; e.g., the turbines did move freely because the bearings did not maintain their original manufactured shape and particulate matter could jam the turbines.

Due to unacceptability of the turbine-based FIM, an alternate methodology using very sensitive thermistors that sense temperature changes based on flow rates was examined in a joint partnership among USARIEM, Medicept, Inc. (Ashland, MA) www.medicapt.com and DesignTurn Inc. (Natick, MA) www.designturn.com. Unresolved issues in fluid accuracy at various temperatures and flow rates led to this concept being abandoned (Montain, personal communication). About this same time development of a hydration monitor (Hydracoach®, Hazlet, NJ) using a turbine sensor that generated electronic pulses when fluid passed the sensor was being developed commercially (www.hydracoach.com/technology/index.html; accessed on 2 October 2008). The Hydracoach® has never been validated and its software is proprietary making it unacceptable for incorporation into a suite of physiological and behavioral monitoring sensors by the military. An alternative approach to these flow-sensor technologies are systems that measure canteen volume through an inductive monitor (15) (http://www.zyn.com/sbir/sbres/sbhist/dodfy05/osd/ osdsb063-ho2.htm; accessed on 19 November 2008 and http://www./SITIS/archives_display_topic.asp?Bookmark=29650; accessed on 19 November 2008). Discussion of this technology is beyond the scope of this report, but it should be noted as a promising alternative to the FIM.

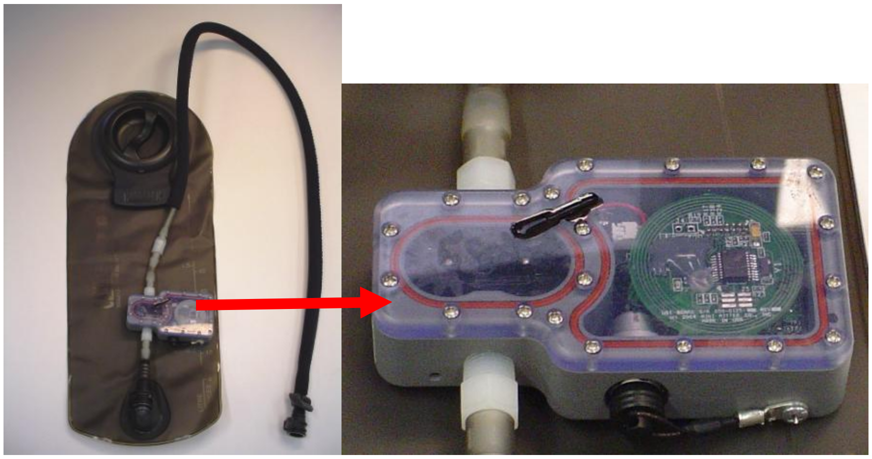
The current version of the FIM was designed in a partnership between USARIEM and ODIC, Inc. (Devens, MA) www.odic.com. This version of the FIM is part of the Warfighter Physiological Status Monitoring – Initial Capability (WPSM-IC) system. It utilizes a gear-based design to achieve accuracy at slow and fast flow rates. The purpose of this report is to document the reliability and validity of the measurements obtained from the prototype gear-based FIM.

METHODS

MATERIALS

Twenty-seven prototype FIM units were evaluated in a bench test, and 15 prototype FIM units were tested in a free-living field test (both described below). The FIM is comprised of two small gears that rotate in response to fluid movement through the drink line (Figure 1); the FIM can be incorporated into modified flexible back-worn hydration systems already in use (Figure 2).

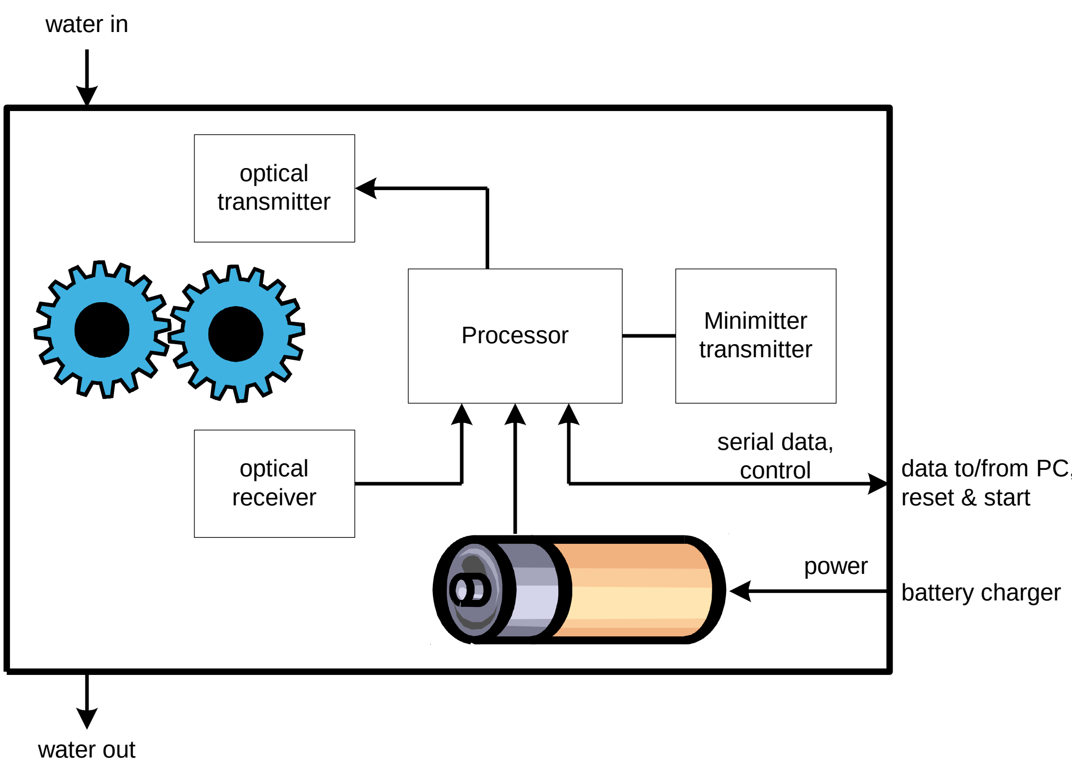
Figure 1. Bladder with Fluid Intake Monitor (FIM) attached to hose of a flexible back-worn hydration system along with close-up view of the FIM



The dimensions of the FIM are 94 mm long x 51 mm wide x 20 mm deep, with a weight of 124.7 g. Fluid consumed through the FIM unit is measured in 0.075 ml increments. Fluid is measured by the amount of movement of the gears as water passes over the teeth of the gears (Figure 3). Optical sensors count the

Figure 2. Modified Camelbak™ hydration system with Fluid Intake Monitor (FIM) inserted into the front pocket of the carrier

Figure 3. Schematic diagram of the Fluid Intake Monitor (FIM)



*Schematic taken from Hickcox, 2005

gear teeth as they turn (14). Measures obtained include date and duration of measurement, sip number, cog gear teeth moved by an individual sip, ml of a particular sip, and cumulative volume displacement. A sip is defined as a period of time after the gears of the FIM have started moving and have not stopped for more than four seconds. The gears will often stop momentarily as an individual swallows the water he/she has just pulled through the system (14). When a delay of greater than four seconds occurs, a second sip is registered. Testing done with some of the systems confirmed the systems worked consistently in the counting of sips using the four second window; i.e., delays less than four seconds would count as only one sip, while delays of greater than four seconds would count as two sips. Information detected by the FIM was transmitted to a computer or to the WPSM hub (a data receiver device with a computer card to record data) through a wireless network (3).

An OHAUS Precision Advanced Scale (OHAUS Corp., Pine Brook, NJ 07058) was used to measure water to one hundredth of a gram (0.00 g). Values were converted into milliliters. Bottled water (Poland Springs, Maine) was used for all testing. Density and volume is minutely affected by temperature of the water. All field testing was conducted between 10ºC and 25ºC while the bench test was conducted at room temperature ~ 22°C. A 0.0026 change in water density was possible. However this source of error is insignificant in this context. Therefore, it was assumed that 1 g of water was equal to 1 ml of water.

BENCH TEST

Bench testing was performed on 27 prototype FIM units at various rates and volumes. A technician performed the test by drawing sips of varying volumes through the hydration system. Ten individual sips were taken from each FIM. Sip volumes were recorded from the FIM. Each sip volume was compared to the volume calculated from the weight of the water removed. The weight change served as the criterion score (i.e., gold standard). The accuracy of the total volume consumed (derived from the summation of a series of individual sips) was also calculated.

The FIM was attached to a personal computer using a hardwire connection in the “diagnostic mode” to display every sip as it occurred using FIM prototype software that logged sip and other status information (time of sip, teeth moved etc.) (14).

FREE-LIVING FIELD TEST

In the free-living field test, 12 volunteers (7 men, 5 women) drank *ad libitum* from the hydration system with the FIM attached to the in-line drink tube. Units that had a greater than 10% error in the bench test total volume assessment were not tested in the free-living field test. A total of 15 FIM units were tested in the field test. The accuracy of measurement objective was that total volume consumed per day would have no more than a ± 5% error (14).

Bladders of the hydration system were filled to capacity with bottled drinking water and weighed prior to and after the test. Volunteers were instructed to use the system *ad libitum* and instructed not to refill or add any fluid to the bladder. Systems were used for up to 48 hours. Systems were returned after each 24 hours and/or when the volunteer consumed all the water in the bladder (whichever occurred first). Once returned, the bladder was removed from the backpack and re-weighed. The difference in weight of the bladder before the volunteer used the system minus the weight of the bladder after the volunteer used the system was the weight of water consumed. This value was then converted to ml of water consumed. Total volumes (ml) recorded by the FIM were compared to the gold standard gravimetric measure of water consumed. A trial was defined as the period from when the bladder was initially weighed to the point at which the bladder was returned after being used and re-weighed. For those individuals who consumed a lot of water, they had two trials per day for a total of four trials over the 48 hours of testing, while those that did not consume as much had only one trial per day. After 24 hours the FIMs were retrieved and weighed even if the volunteer did not consume all the water in the bladder.

DATA ANALYSES

Reliability of Measures

A test-retest intraclass reliability analysis **of the percent difference in volumes** between the FIM-determined volume and the gravimetrically measured (gold standard) volumes was performed to assess consistency of measures. Since the gold standard measure should not vary appreciably given the accuracy of the scale used, test-retest differences in percent error could be attributed to the FIM. The analysis was done on a percent difference basis because actual sip differences in the bench test and total volume differences in the field test varied from trial to trial.

A repeated-measures analysis of variance (ANOVA) was calculated between the **percent difference volumes** to determine if changes in error volume measured over sips varied significantly. This measure allowed us to determine stability of error in volume measurements across trials. Control charts (27) by individual FIM units allowed differences in the manufacturing process between units to be determined. A coefficient of variation (CV) was also calculated for the field test assessments of the percent difference obtained to show the amount of variation as a function of calculated mean percent error.

Validity of Measures

The volume of water measured by the FIM was compared against the gravimetrically measured volume change using a paired t-test. Volumes in water recorded by the FIM were also plotted against the actual weight change, and regression analysis was performed to predict FIM accuracy. A perfect fit would have values plotted close to the line of identity extending out from the origin of the scatter plot signifying the FIM calculated measures were valid. A Bland-Altman plot (2) was also constructed to show the difference between individual measures by the two methods (i.e., FIM Measure – Gold Standard Measure) versus the mean value of the two measures. Upper and lower limits, i.e., the limits of agreement, are formed by $\bar{d} \pm 2sd$, where $\bar{d}$ is the mean difference and *sd* is the standard deviation of the difference. The volumes from the FIM are determined to be accurate if 1) the overwhelming majority of (FIM – Gold Standard) measures are within the limits of agreement, 2) the measured differences (FIM Measure – Gold Standard) are small compared to the overall volume of water consumed, and 3) $\bar{d}$ is close to zero. The field test total volumes should also be within $\pm$ 5%, the pre-established objective criterion.

RESULTS

BENCH TEST

Reliability of Measures

Examining the stability of measures from the individual sip test by repeated measures ANOVA showed there was a significant ($p < 0.0001$) difference between sips (Table 1). These results do not include one FIM unit that was jammed and failed completely. When a sip was taken, the FIMs recorded it 100% of the time. The only significant difference from post-hoc Least Significant Difference tests shows that Sip 1 is significantly different $p < 0.01$ from the other sips, while Sips 2 through 10 did not differ significantly from one another. Five units had error values greater than 10% when all ten sip error values were averaged. The intraclass reliability analysis produced a significant ($p < 0.001$) intraclass coefficient (ICC) of 0.83 over trials when examining error values of Sips 2 though 9. Sip 1 was not included because of the significantly different volume that was recorded.

Table 1. Mean Difference Between Fluid Intake Monitor (FIM) and Gravimetric Measures for 10 Consecutive Sips.

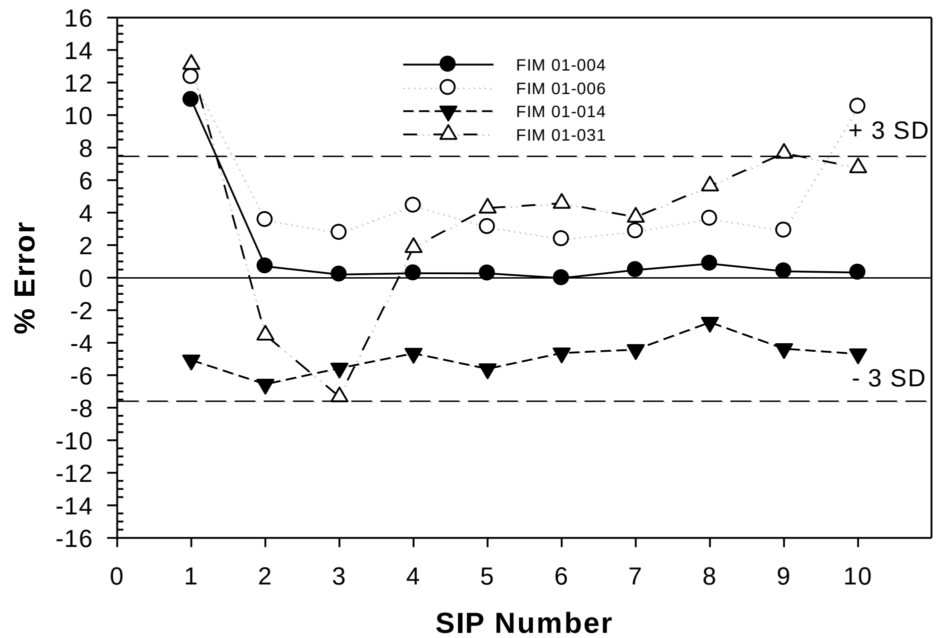
Sip	Actual Water Consumed Mean ± S.D. (ml)	Error in FIM Measurement Mean ± S.D. (ml)	Absolute % Error
1	43.5 ± 6.5	6.1 ± 7.2	14.0
2	23.9 ± 6.2	-1.0 ± 2.1	4.1
3	23.5 ± 6.3	-0.8 ± 2.2	3.4
4	23.3 ± 4.8	-0.3 ± 2.2	1.3
5	24.0 ± 5.6	-0.3 ± 2.3	1.3
6	23.7 ± 7.1	-0.3 ± 2.0	1.3
7	23.0 ± 6.3	-0.9 ± 3.7	3.9
8	23.0 ± 5.5	-1.0 ± 5.6	4.3
9	21.7 ± 6.0	-0.5 ± 3.0	2.3
10	26.2 ± 8.8	-0.3 ± 3.3	1.1

*A positive value indicates the FIM measured more water than actually consumed, while a negative value indicates the FIM measured less water than actually consumed.

Validity of Measures

The mean amount of water consumed and measured by the scale per sip during the bench test was 25.6 ± 8.7 ml. The FIM recorded 25.7 ± 10.7 ml per difference. The mean difference was 0.1 ± 4.2 ml per sip, which was not significant. Figure 4, a variant of a control chart (27) shows sip-by-sip errors of four typical FIM units. The upper and lower control limits are ± 3 SD calculated for all ten sips for all FIM units tested, as recommended by Shewert (27). The center line represents zero percent error; and while this differs from a typical control chart, where the actual mean error would be plotted, it is used here to illustrate under-recording by some FIM units and the over-recording by others. Note the differences between the 4 FIM units. Sip 1 for FIMs 004, 006, and 014 illustrate that this measurement exceeds the three standard deviation limit. Sips 2 through 10 for FIM 004 show very little error. FIM 006 shows a consistent over-consumption recording while FIM 014 shows a consistent under-recording error. FIM 031 is inconsistent in the percent and direction (under or over) of its error across all ten sips. Within Appendix A are control charts for each FIM unit.

Figure 4. Control chart variant illustrating percent error of each sip



*Control charts were developed by Shewhert (27). The upper and lower control limits are ± 3 SD units. This chart is not actually a control chart because on this chart the center line represents zero percent error, which differs from an actual control chart where the actual mean error would be plotted.

A Bland-Altman plot (Figure 5) illustrates the relationship of FIM measures to the gold standard, with 2.3% of sips under-measured by the FIM and 4.7% of sips over-measured by the FIM by at least ± 2 SD units.

Figure 5. Bench test: Bland-Altman plot of sip volumes: Fluid Intake Monitor to the Gold Standard

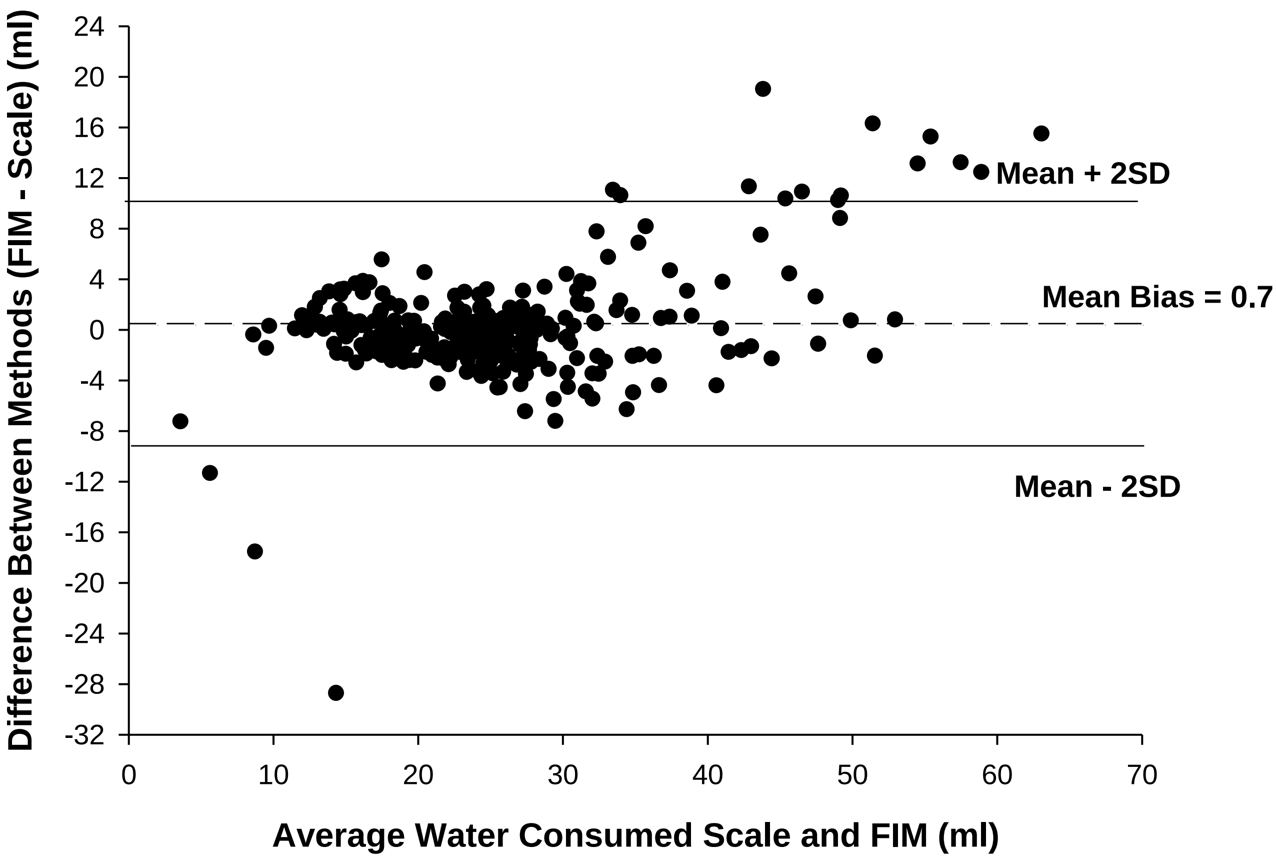


Table 2 summarizes the total volume of water from the 10 sips drawn during the bench test for each FIM and the error associated with that FIM unit. When examining the total volume of the ten sips by FIM unit, a large variation in the percent error was recorded. The volumes were in error by as little as 0.5% to as much as 18.8%; one device completely malfunctioned and did not record any values (this device was not included in the analyses). Two units had error rates greater than 10%, one under-reported the amount of fluid consumed by 18.8%, and one over-reported the amount of fluid consumed by 11.1%.

Table 2. Total Volume of Individual Sips and Percent Error for Each Fluid Intake Monitor (FIM) and Gravimetric Measure for 10 Sips.

Fluid Intake Monitor (FIM) #	**Total Volume of Sips (ml) From FIM**	**Total Volume of Sips (ml) Actual From Scale Weight**	**% Error***
01-004	179.3	165.0	8.7
01-005	203.1	187.2	8.5
01-006	146.9	180.9	-18.8
01-007	305.9	292.5	4.6
01-010	308.3	267.2	5.8
01-011	269.4	266.0	1.3
01-013	290.5	292.2	1.7
01-014	222.5	244.6	-9.1
01-015	294.5	270.6	8.8
01-016	281.0	258.9	8.5
01-017	305.0	303.5	0.5
01-018	286.3	275.3	4.0
01-019	206.8	226.2	-8.6
01-021	247.1	268.4	-8.0
01-022	0.0	242.4	-100.0
01-023	330.9	340.2	-2.7
01-024	228.6	228.6	-4.1
01-025	273.4	263.1	3.9
01-026	250.9	276.0	-9.1
01-027	325.3	297.9	9.2
01-029	198.3	207.1	-4.3
01-030	261.7	272.2	-3.8
01-031	367.8	331.0	11.1
01-032	230.3	241.3	-4.6
01-033	268.0	292.9	-8.5
01-034	228.2	240.4	-5.1
01-035	221.0	232.3	- 4.9
Mean $\pm$ SD	249.3 $\pm$ 70.9	257.9 $\pm$ 42.2	-4.3 $\pm$ 20.5

*****A positive value means the FIM measure was more than the weight measure, i.e., it over predicted how much water was consumed, while a negative value means the FIM measure was less than the weight measure (i.e., it under-predicted how much water was consumed).

FREE-LIVING FIELD TEST

<u>Reliability of Measures</u>

Reliability is composed of both stability and consistency of measures. Stability of measures is the change in the percent error score from Trial 1 to Trial 2 for the 13 FIM units where two trials were completed. The mean percent error of the FIM calculated by comparing its recorded value to the gravimetric measurement was -3.3 $\pm$ 12.8% for Trial 1 and -5.7% $\pm$ 19.0% for Trial 2. This difference was not statistically significant. The CV between Trial 1 and 2 was a very large 291.1%, indicating great variability between FIM units which may partially account for the lack of significance between trials. Intraclass reliability assesses the consistency of measures. The ICC between trials was non-significant and low (ICC = 0.48) indicating low consistency of measures.

<u>Validity of Measures</u>

The mean amount of water consumed as measured by the scale was 1740.2 $\pm$ 462.2 ml per trial. The FIM recorded 1671.5 $\pm$ 546.0 ml per trial. The mean difference was 68.7 $\pm$ 319.0 ml per trial, which was not significant. The Bland-Altman plot (Figure 6) shows the relationship between the FIM and the gold standard measurements. The mean absolute percent error of the FIM measurement compared to the scale measurement was 10.3 $\pm$ 2.2%. However, six trials exceeded the absolute value error of 15%. Four of these trials had the FIM under-measuring water flow by 29.4%, 36.1%, 44.7%, and 47.1%, and two trials had the FIM over-measuring water flow by 15.5% and 16.6%. Figure 7 shows the regression analysis and associated prediction equation. Large corrections are needed to the FIM measurements, for example adding 590 ml to the observed measurement allows for the best prediction. Yet, even with doing that, 12 of the 31 measurements fall outside the 95% regression prediction intervals. These measurements contribute significantly to the unexplained variance (34%). Values that are far from the line of identity indicate error in the FIM measurements given that the gold standard gravimetric method is accurate.

Figure 6. Free-living field test: Bland-Altman plot of Fluid Intake Monitor (FIM) water consumption compared to weight loss method of water consumption *n* = 31 measurements. Mean bias (i.e., milliliter of water consumed FIM – gravimetric Method) was 69 ml, and the mean error (SD of individual differences between FIM and gravimetric measurements) was 319 ml.

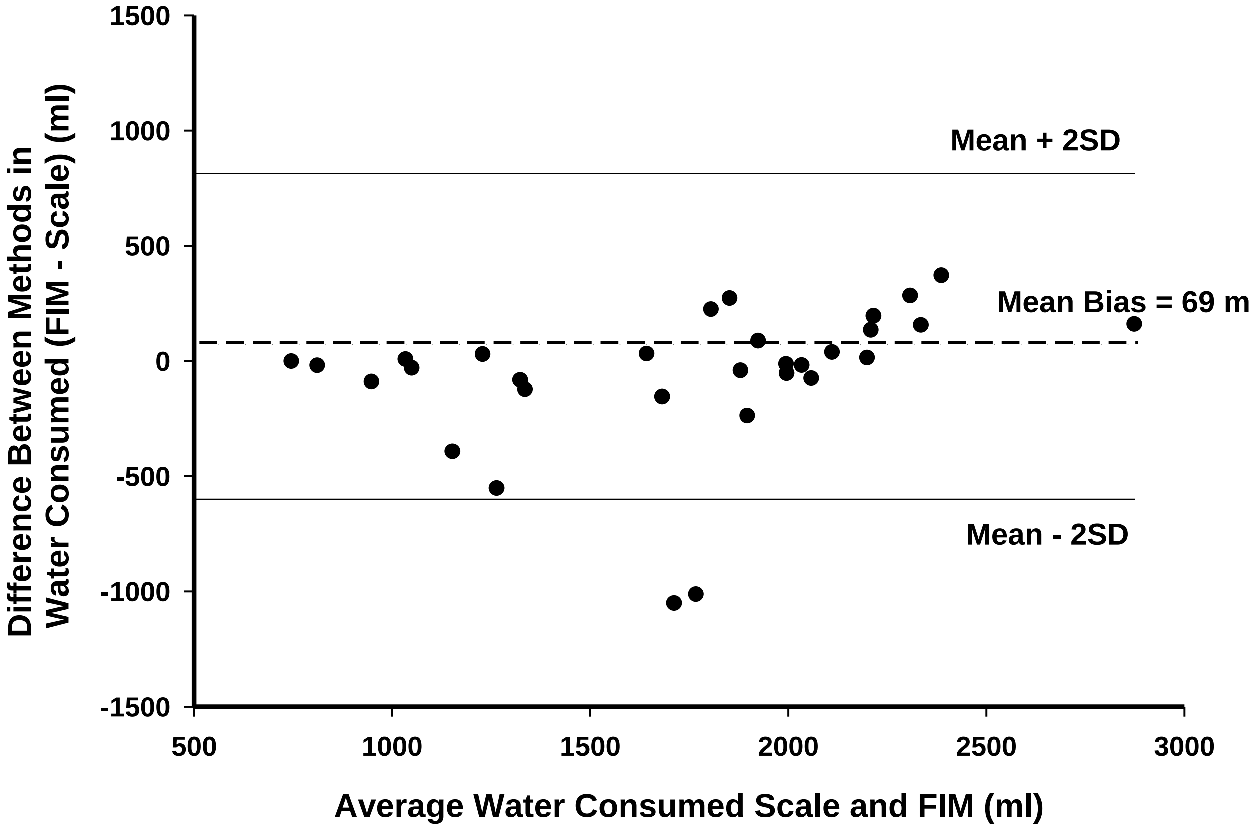
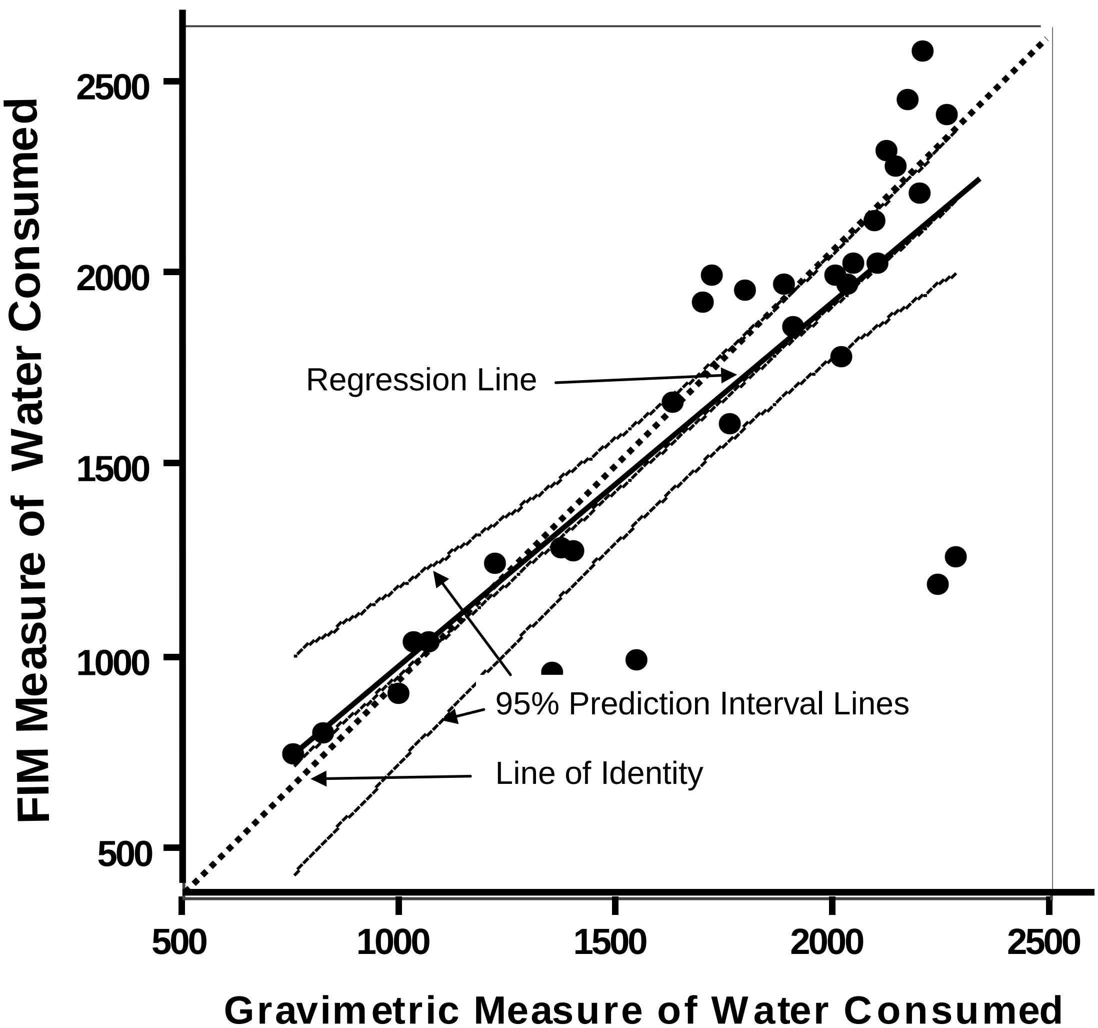


Figure 7. Free-living field test: Scatter plot and regression analysis showing the relationship of water consumption measured by the Fluid Intake Monitor (FIM) versus that measure by the gold standard gravimetric method.



Water Consumed (ml) = 590.83 + 0.69 * [FIM measured water consumed (ml)]

$R^2 = 0.66$

*Linear Regression with 95% Mean Prediction Interval

DISCUSSION AND CONCLUSIONS

BENCH TEST

Bench test results show that with the exception of the first sip, average measurement error was small (i.e., less than 5%). An intraclass coefficient of 0.83 showed there was good consistency in the measurements from sip to sip after Sip 1. While the overall reliability of the sample of FIM units showed relatively good consistency across sips, for sips 2 through 10, the accuracy of the individual units varied considerably (Figure 4). Some units, particularly FIM 031, were highly inconsistent in recording fluid consumed, and one unit malfunctioned completely.

The fact that, after the first sip, there is generally good consistency across sips suggests the fundamental gear design was acceptable. However, the variable accuracy of these prototypes, and the two highly dysfunctional units, indicated the presence of manufacturing defects that need to be addressed. The present prototype FIM units were machined by hand, and consistently machining the pairs of gears presents obvious challenges. Presumably, FIM performance could be significantly improved if the gears were manufactured more accurately and precisely (e.g., using injection molding) and using a suitable type of plastic (e.g., durable, impervious to water, density near that of water, suitable for use with potable water, low coefficient of thermal expansion).

The relatively high error rate or overestimation on the first sip (~ 14%) can be attributed to an initial presence of air in the hose between the water filled bladder and the FIM. When a drinking action caused the air in the hose to move over the gears, the gears spun at high speed, resulting in an artificially high reading on the first sip. The FIM incorporates a check valve to prevent water backflow into the drinking bladder. However, the valve is not completely air tight, allowing air to enter the hose when the system was not in active use. After the first sip, once the system was primed and water filled the entire system, this source of error was not present. Future FIM design modifications should address this issue, either by making the backflow check valve air tight, or by introducing a correction factor when the rate of rotation of the gears is artificially elevated. In the broad scheme, the relatively small amount of error associated with the first sip, when compared to a whole bladder's worth of water consumption, is inconsequential when monitoring Warfighter water consumption.

FREE-LIVING FIELD TEST

A goal of no more than a ± 5% measurement error in estimated fluid consumption was set for the field test. This objective was achieved on only 14 of the 31 trials or 45.2% of the time. Only three FIM units were within the ± 5% error for all their trials during the field test. The inconsistent measurement of fluid intake by the FIM during free living use was reflected by the low ICC (0.48) and large CV (291%). Even though only the 15 best-performing units were included in the field test, some FIM units appeared to work reasonably well while others were problematic, as in the bench tests.

Regression analysis showed that the FIM estimate of water consumption could be improved by using a prediction equation (i.e., water consumed (ml) = 590.83 + (0.69 x [apparent water consumption in ml]) ($R^2 = 0.66$). Ideally, the slope of the regression equation should be closer to the line of identity (1.0) with a smaller intercept correction factor. Even when using this corrective equation, 34% of the variance in the measurements is still unexplained, and 12 of 31 points fell outside of the 95% prediction interval (Figure 7) indicating the difficulty in calculating the amount of water consumed as measured by the FIM.

The results of the field test showed that the FIM, when used by free-living individuals, produced neither reliable nor valid measurements (a device may produce reliable measurements that are still not valid). Consistent error or offset in the FIM measurements can be corrected through adjustments in software. However, the unreliability of these prototype FIMs limited the value of this approach. Providing a single corrective equation to all the units did not provide the needed improvement in accuracy.

On a positive note, bench testing demonstrated that the current FIM prototype accurately detected each sip event 100% of the time (although the estimated volume of the sip might not be accurate, as stated above). The ability to reliably detect drinking events, particularly when combined with other measures, could provide useful insights into the health status of a sick or injured Warfighter being monitored on the battlefield or in training from a remote location.

Minor mechanical reworking of these FIM prototypes had little impact on the accuracy of the units. A mechanical bench test showed the re-worked units still had errors greater than $\pm$ 10% (4). However, the mean error rates for the systems tended to be consistent, indicating the re-worked FIM prototype systems were reliable but not valid. A software fix may be possible with the current design. However, this test was a controlled mechanical test. Future work should include a repeat of a mechanical bench test, similar to the one done by Caderette (4), whereby a measured amount of fluid was pulled through the system with a syringe. Tests like this should be done at different water temperatures and after software and/or hardware fixes are made to the system. Testing should also include human bench and field testing, as sip signatures (the amount and rate of water sipped) are different compared to a mechanical pump or a syringe that pulls water through the system. Furthermore, differences in sip signature patterns among people, and even within the same person, vary. A functional system must be reliable and valid for all individuals and their individual drinking behavior. In summary, both hardware and software fixes to the problem of accurately measuring fluid consumption through the FIM should be considered.

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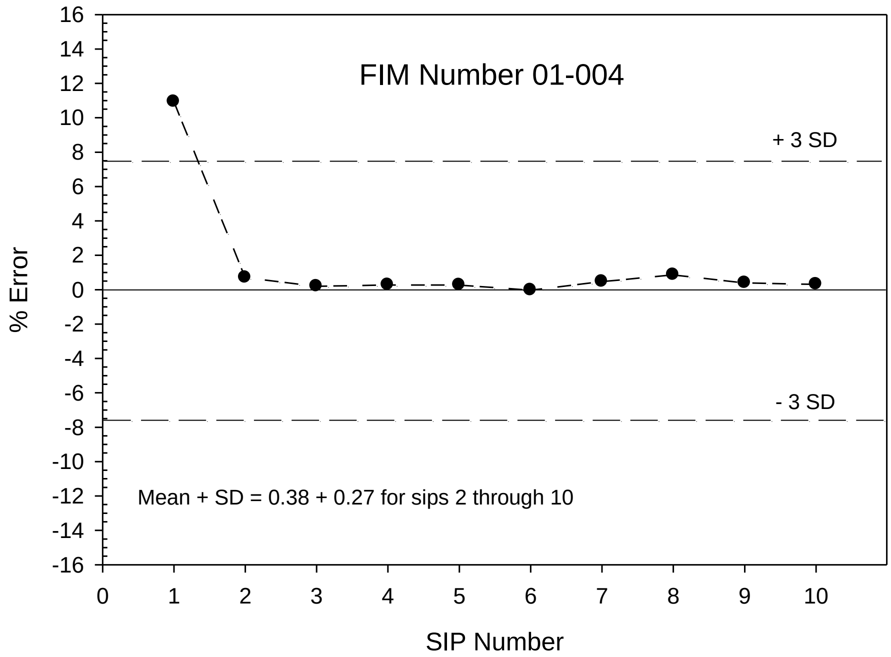
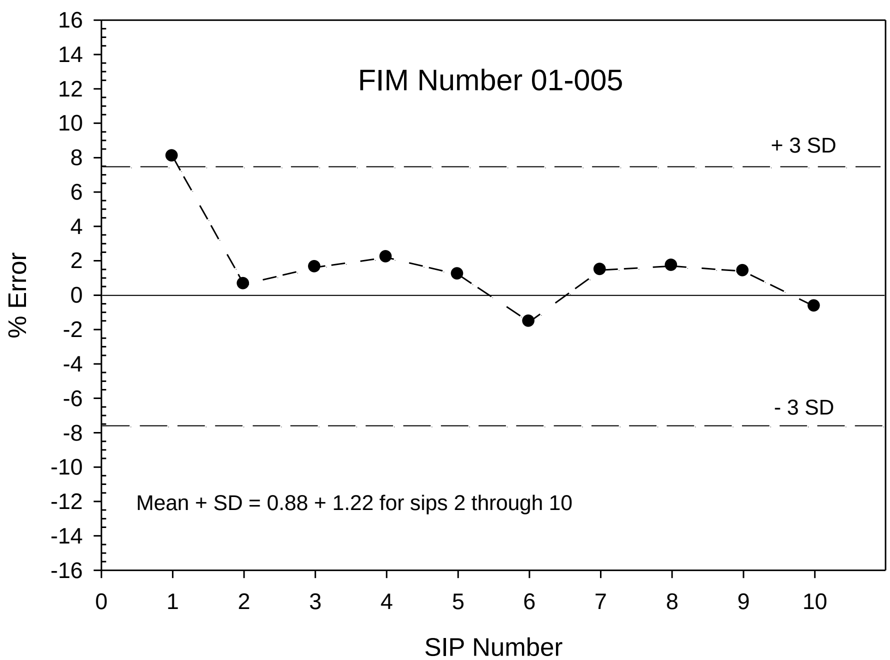
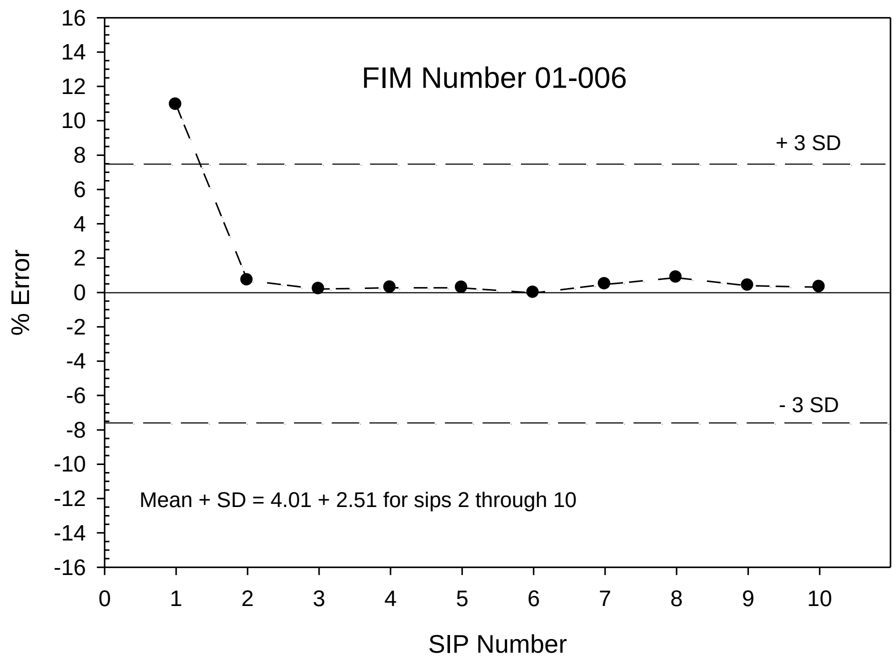
APPENDIX A: Control Charts for Each Fluid Intake Monitor (FIM) and the Individual Percent Error for Each Sip



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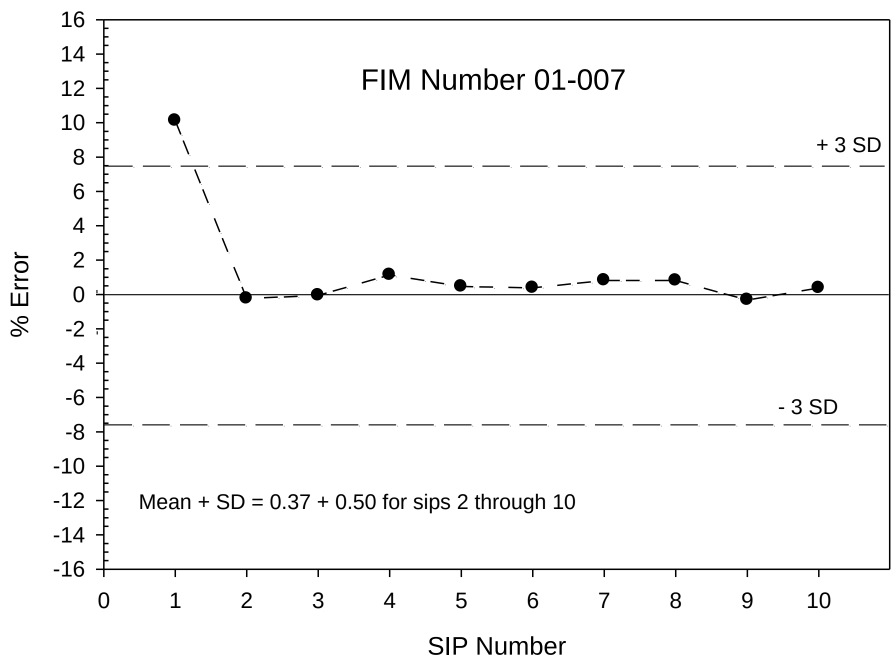
+ 3 SD
- 3 SD
Mean + SD = 4.01 + 2.51 for sips 2 through 10
% Error
SIP Number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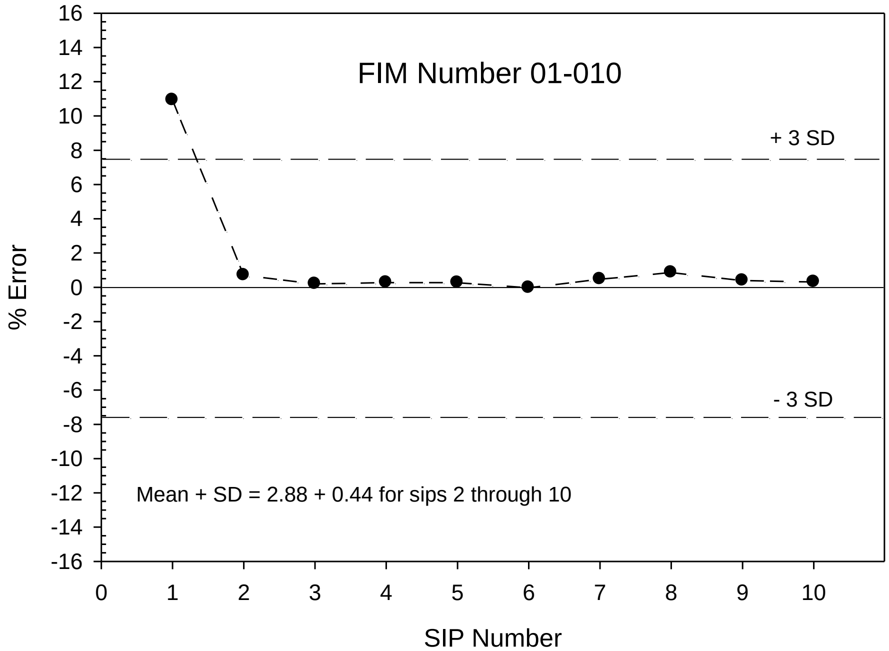
- 3 SD
Mean + SD = 0.37 + 0.50 for sips 2 through 10
% Error
SIP Number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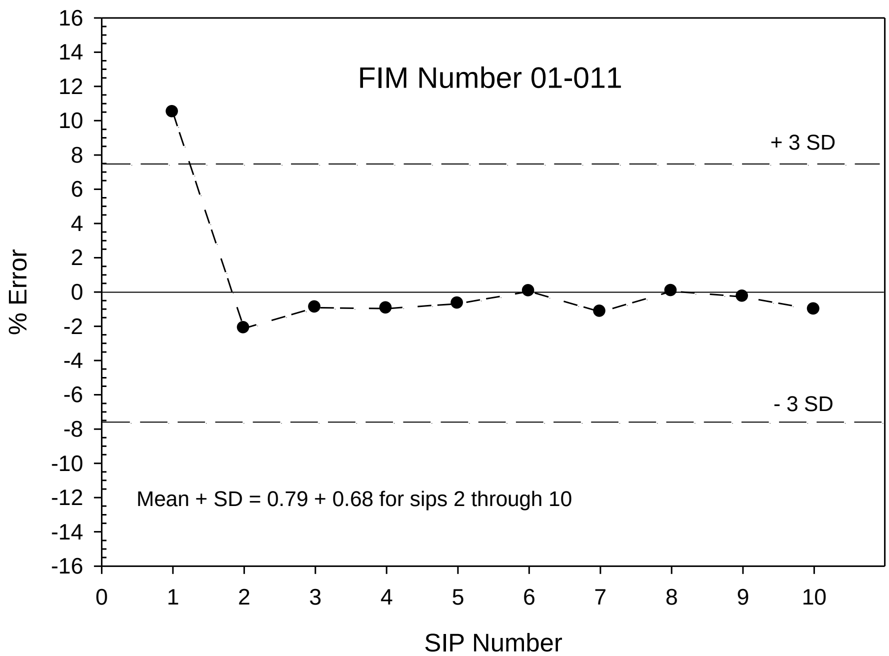
- 3 SD
Mean + SD = 2.88 + 0.44 for sips 2 through 10
% Error
SIP Number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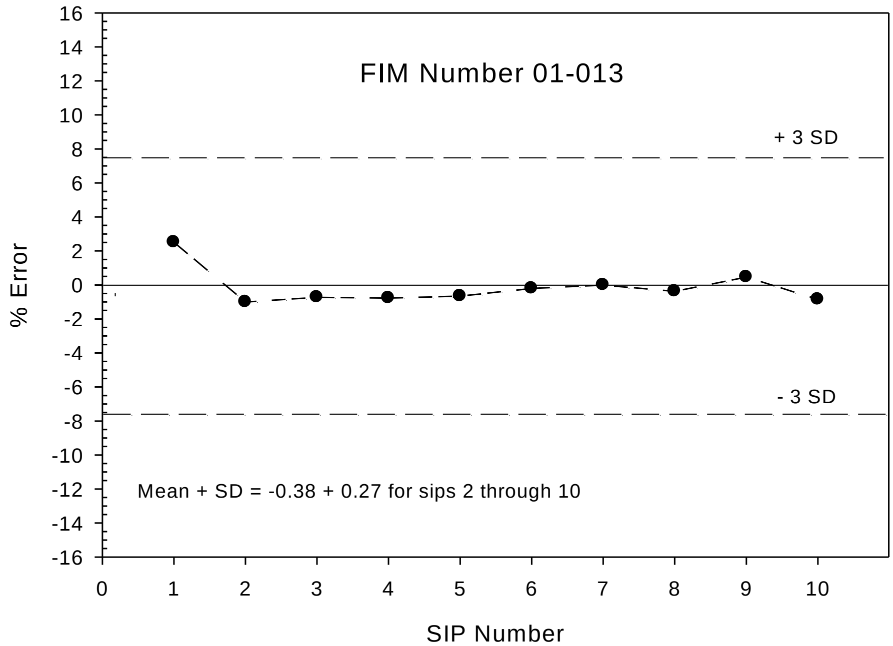
+ 3 SD
- 3 SD
Mean + SD = 0.79 + 0.68 for sips 2 through 10
% Error
SIP Number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- 3 SD
Mean + SD = -0.38 + 0.27 for sips 2 through 10
% Error
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14
12
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8
6
4
2
0
-2
-4
-6
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-10
-12
-14
-16
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1
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3
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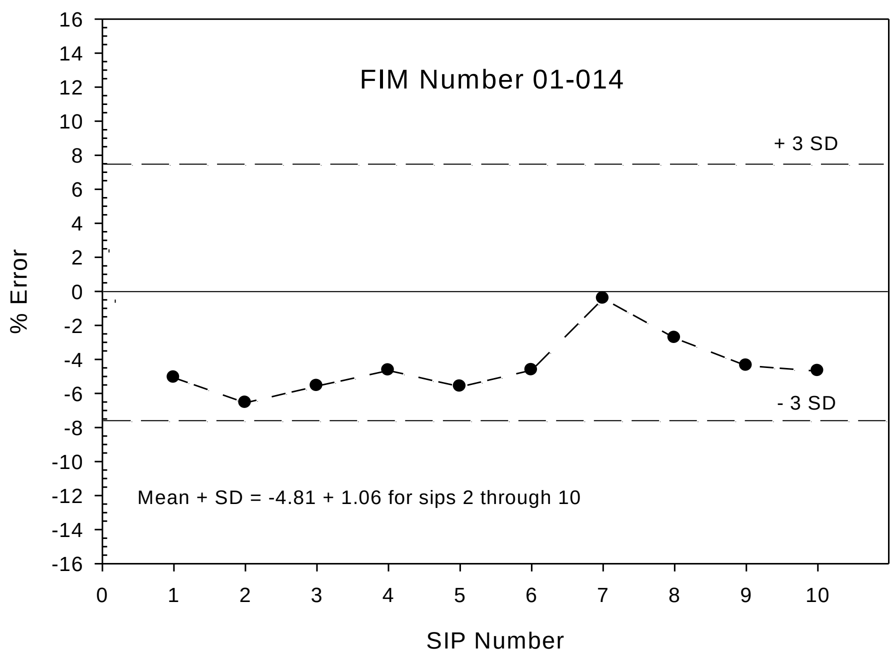
7
8
9
10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- 3 SD
Mean + SD = -4.81 + 1.06 for sips 2 through 10
% Error
SIP Number
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14
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8
6
4
2
0
-2
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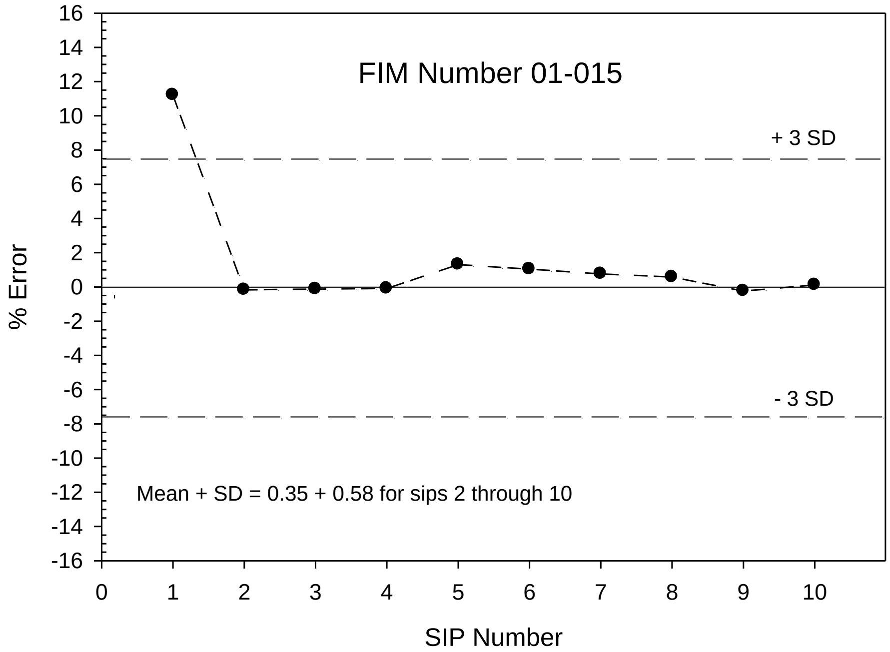
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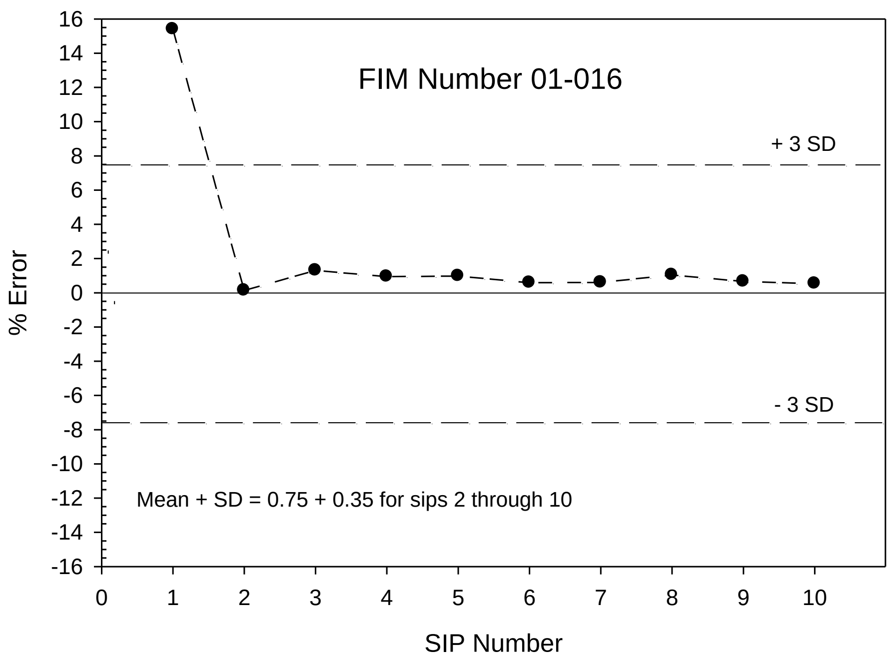
Mean + SD = 0.35 + 0.58 for sips 2 through 10
% Error
SIP Number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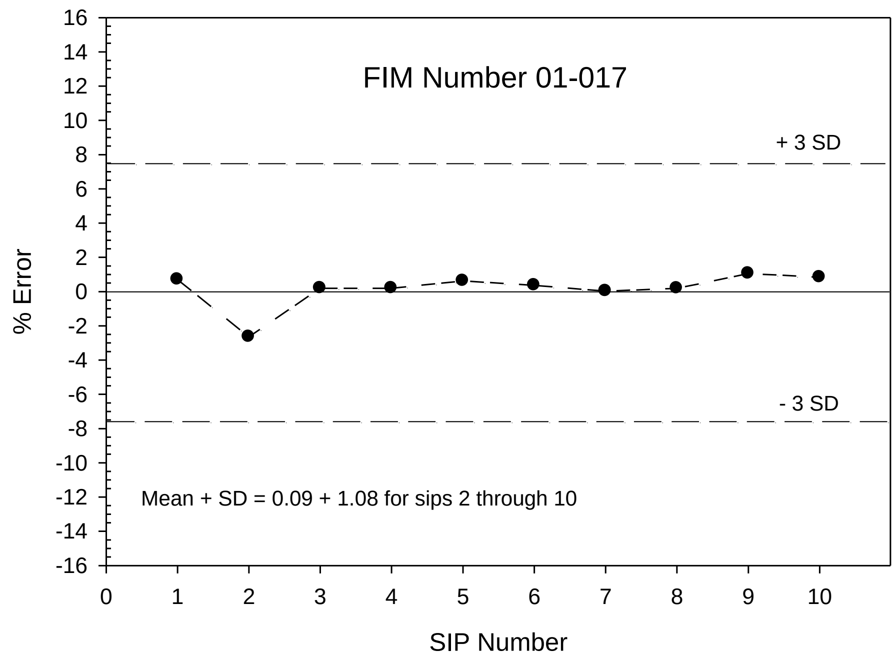
SIP Number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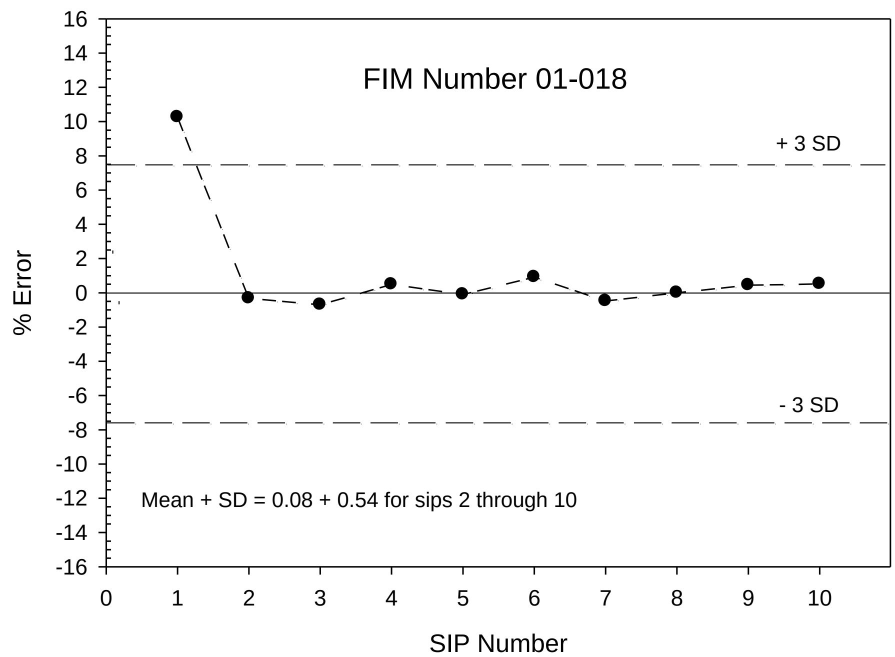
Mean + SD = 0.09 + 1.08 for sips 2 through 10
% Error
SIP Number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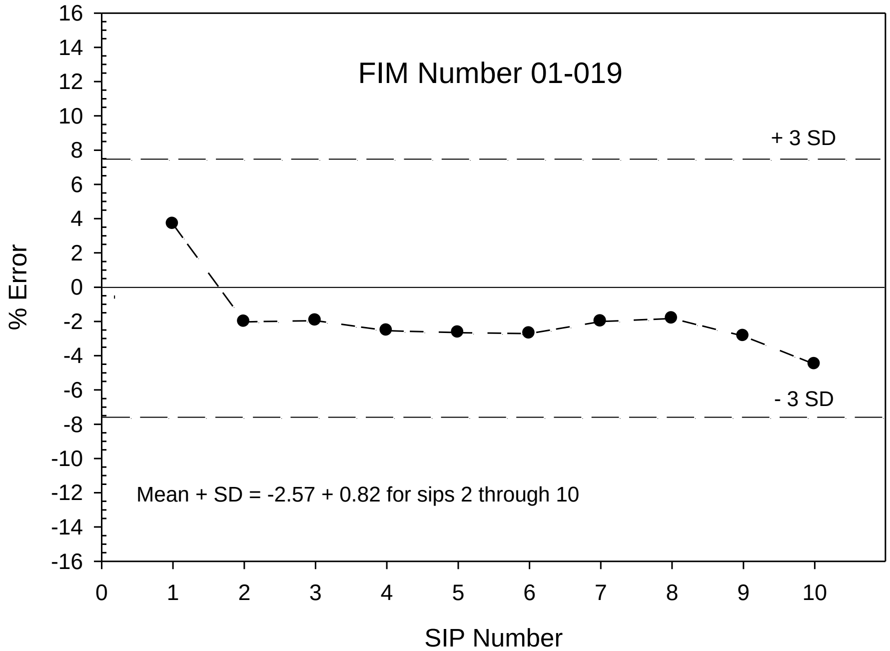
SIP Number



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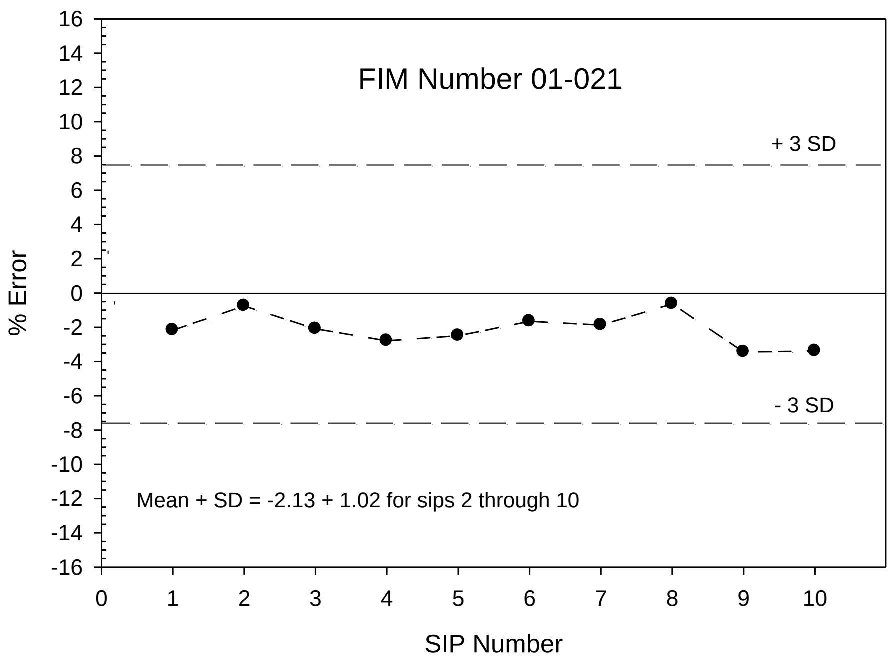
% Error
SIP Number



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Mean + SD = -2.13 + 1.02 for sips 2 through 10
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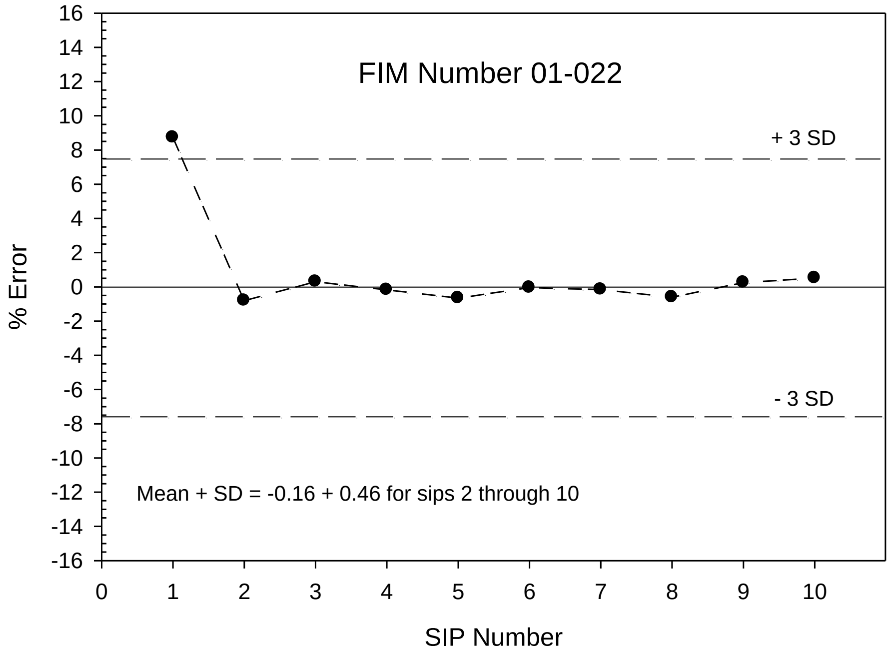
SIP Number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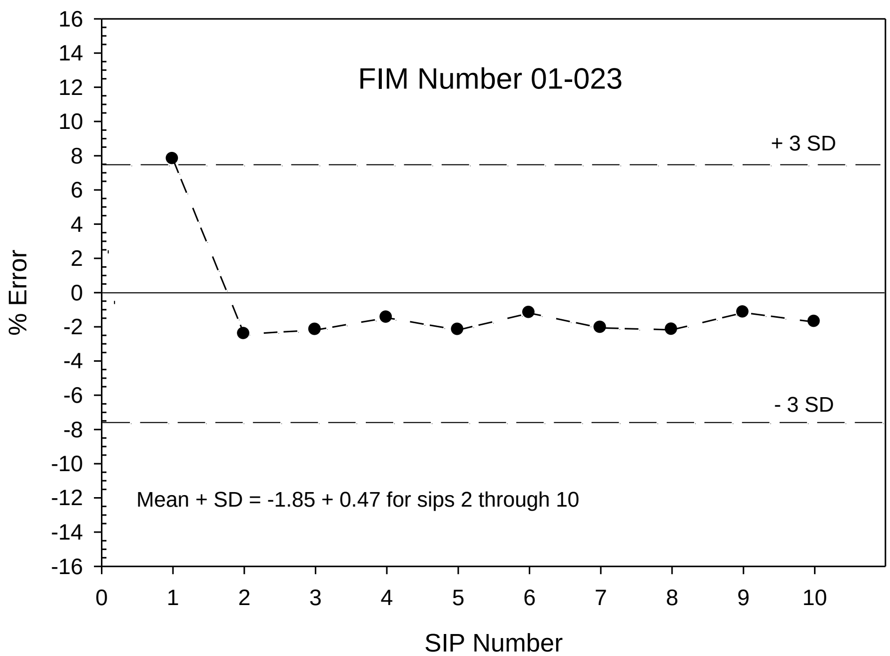
- 3 SD
Mean + SD = -0.16 + 0.46 for sips 2 through 10
% Error
SIP Number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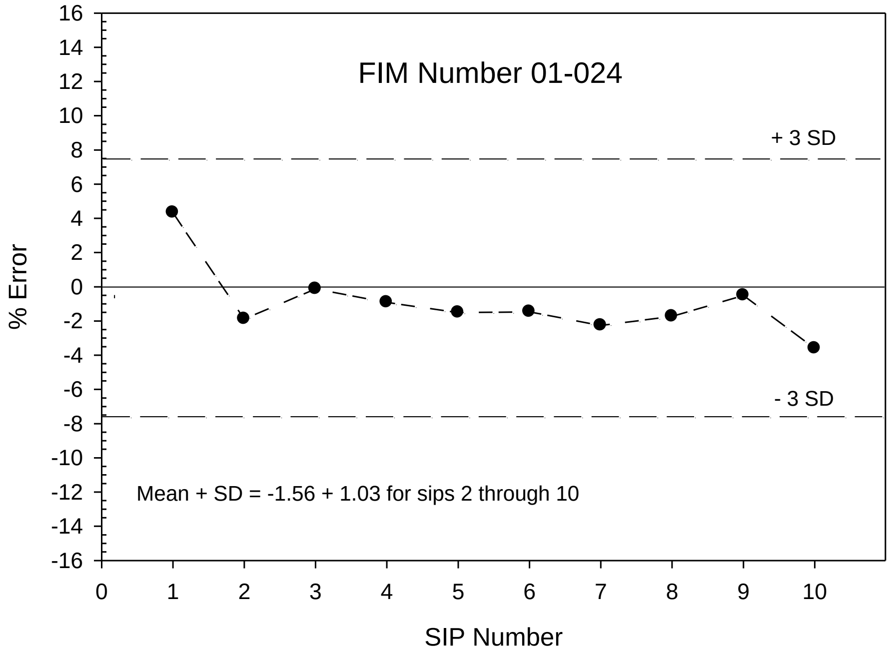
SIP Number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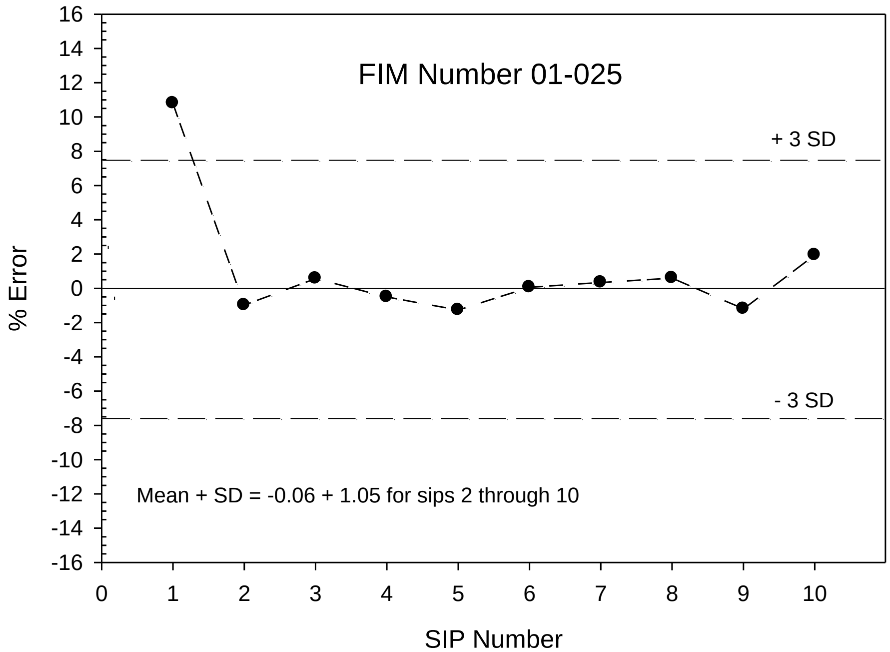
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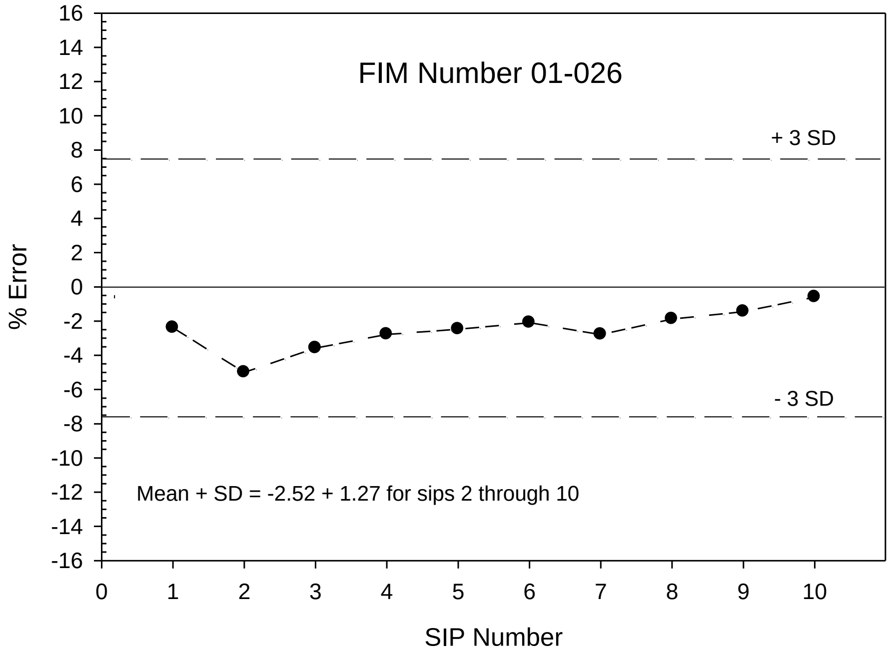
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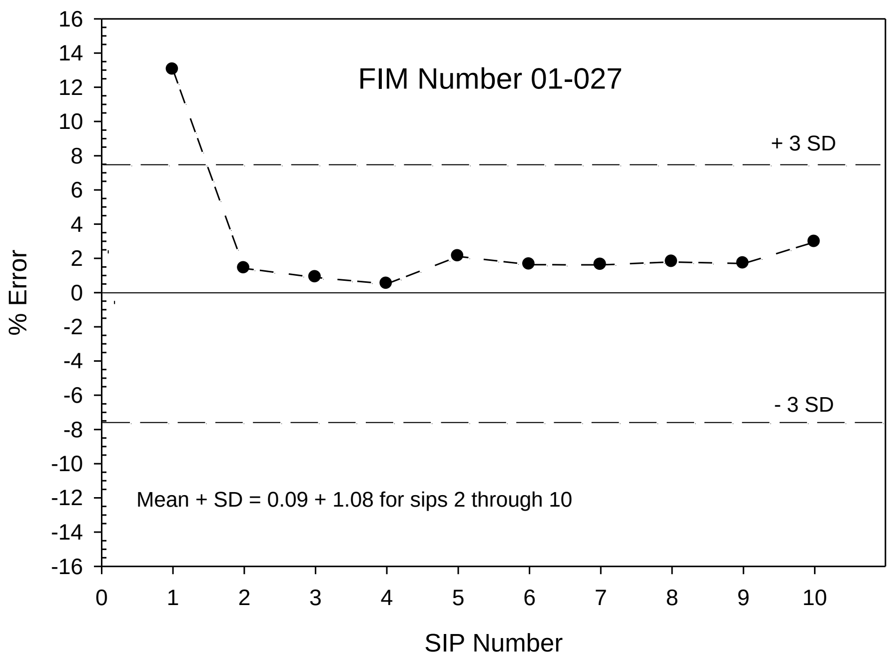
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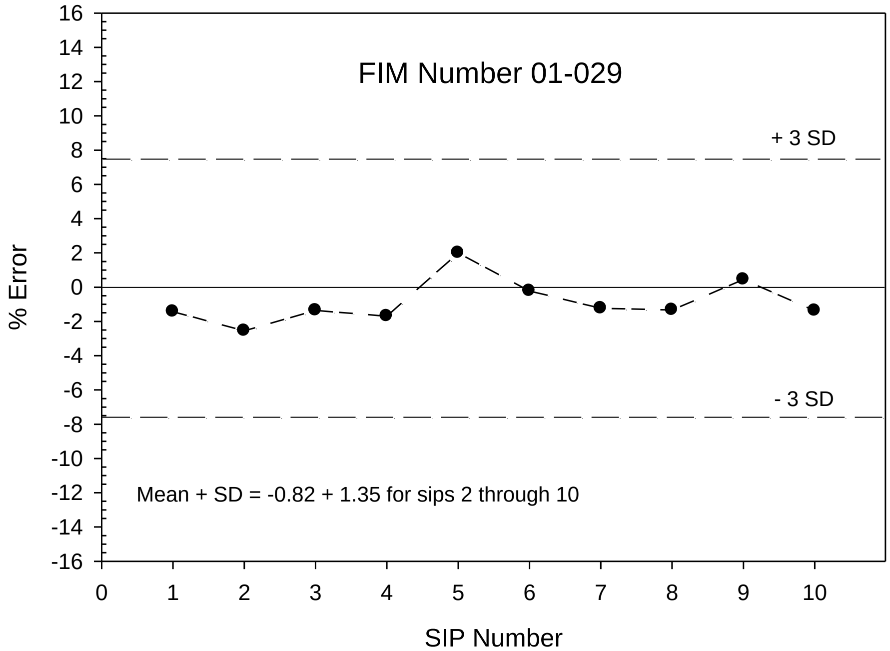
Mean + SD = 0.09 + 1.08 for sips 2 through 10
% Error
SIP Number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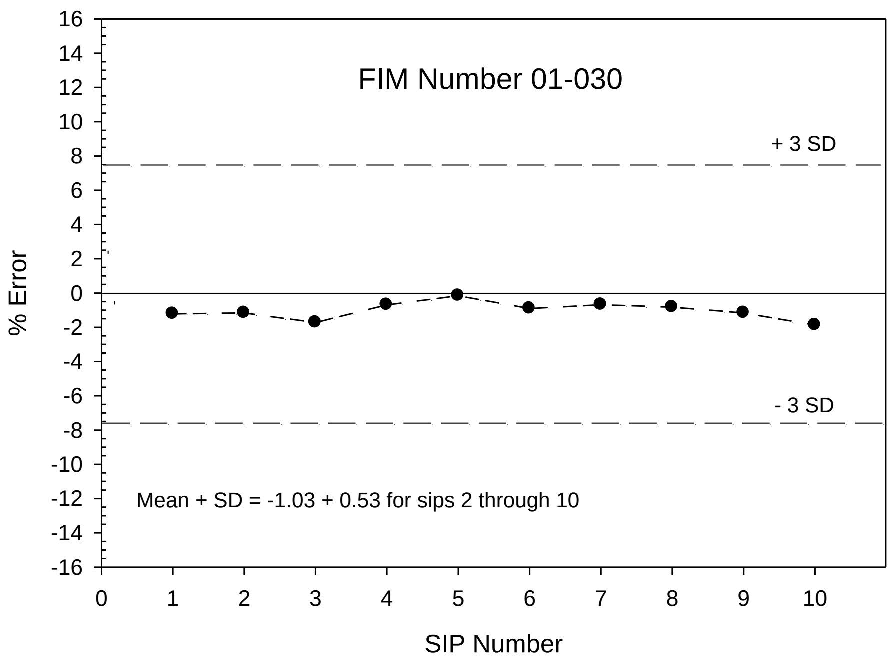
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Mean + SD = -1.03 + 0.53 for sips 2 through 10
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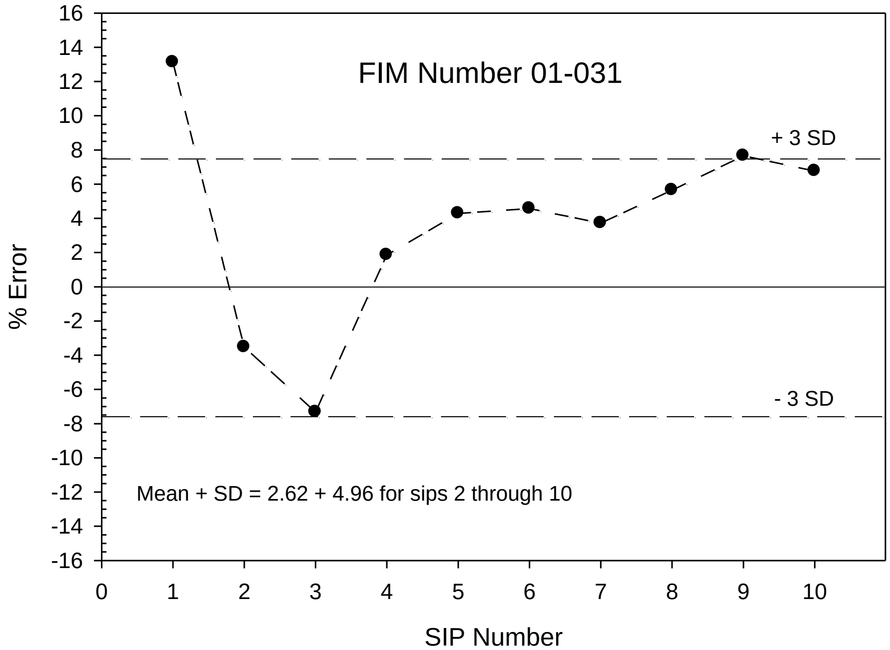
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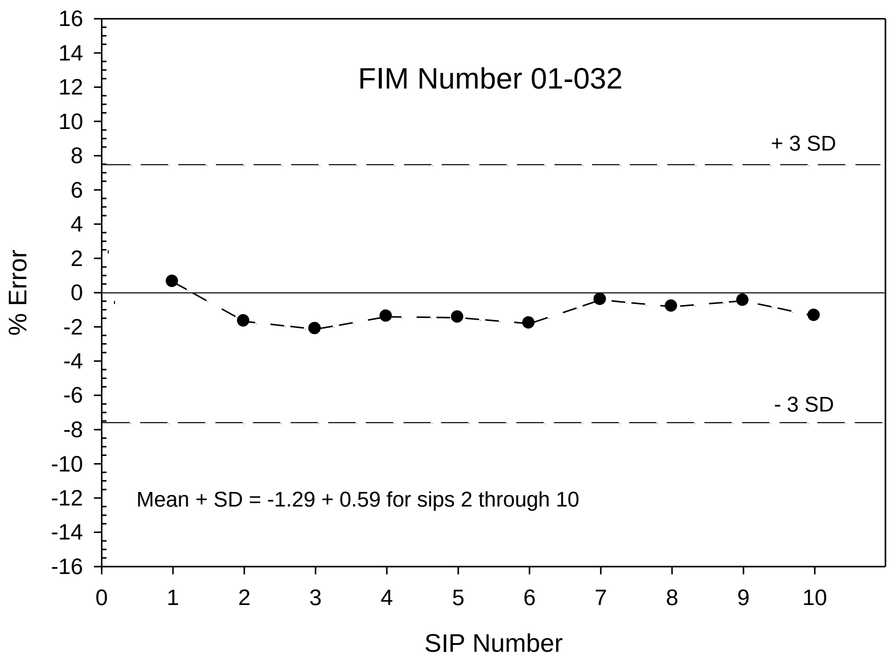
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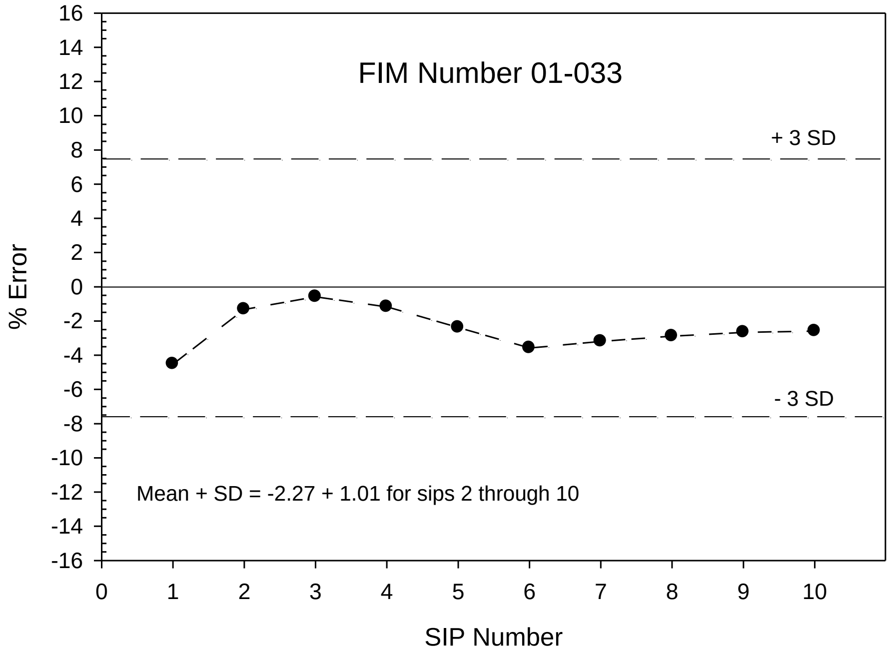
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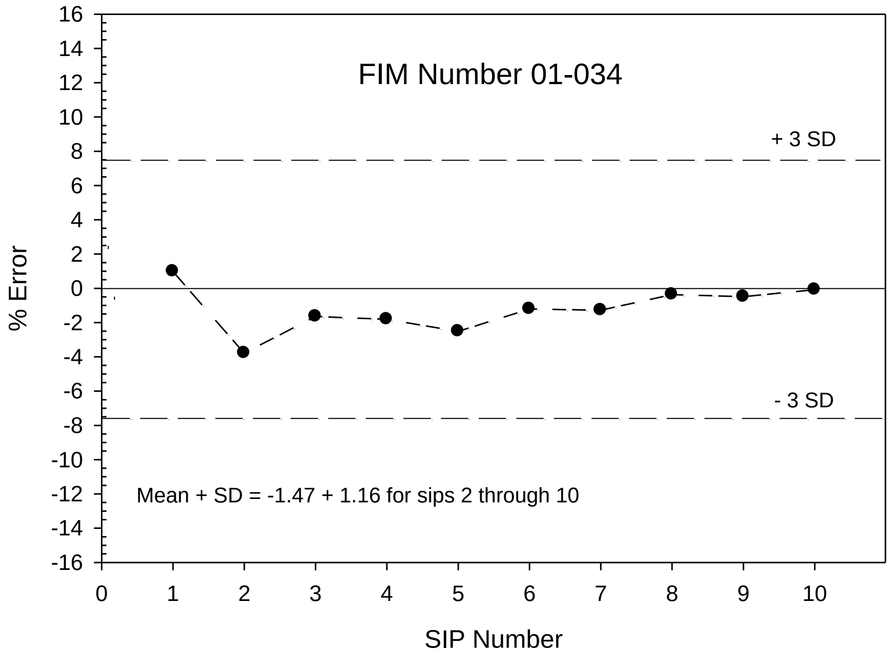
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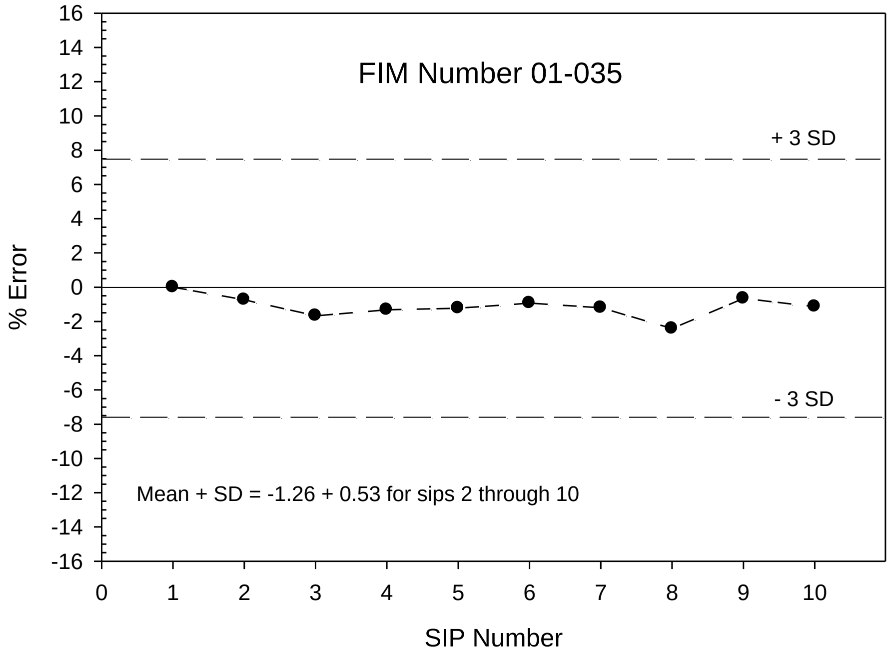

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Mean + SD = -1.26 + 0.53 for sips 2 through 10
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